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EXAMINER	
CROUCH, DEBORAH	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
01/03/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/523,643	EULENBERG ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,18-26,33,34 and 36-44* is/are pending in the application.

4a) Of the above claim(s) *2-10,18-26,33,34 and 36-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election with traverse of group III, claims 1 and 11-15 in the reply filed on October 10, 2007 is acknowledged. The traversal is on the ground(s) that the restriction requirement is based on U. S. practice whereas the application is a national stage application filed under 35 U.S.C. § 37.1. Applicant also argues there was no lack of unity of invention in the international PCT application. Applicant is correct in stating the incorrect practice was employed in setting forth the restriction/election requirement mailed July 9, 2007. A proper grouping of the claims is set forth below. However, there is no requirement that a U.S. examiner follow the lack of unity practice of another examiner. Although the restriction/election requirement is not being made final so that applicant may respond, application cannot elect a new invention for examination. A proper restriction/election requirement is set forth below, substituting for that mailed July 9, 2007. The formal paragraphs are not repeated but carry over.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1, 9, 11-15, 33, 36 and 38, 40, drawn to a pharmaceutical composition comprising a minibrain homologous protein and or a functional fragment thereof; a kit; and use for the treatment of obesity, diabetes and metabolic syndrome.

Group II, claims 1-7, 11-15 and 33, drawn to a pharmaceutical composition comprising a nucleic acid molecule encoding a minibrain homologous protein and/or a functional fragment thereof; and a kit.

Group III, claims 1 and 11-15, drawn to a pharmaceutical composition comprising a modulator of a nucleic acid molecule encoding a minibrain homologous protein and or a functional fragment thereof; and a kit.

Group IV, claim 1 and 11-15, drawn to a pharmaceutical composition comprising a modulator of a minibrain homologous protein and or a functional fragment thereof; and a kit.

Group V, claims 18, 19 and 43, drawn to a transgenic animal exhibiting increased expression of a minibrain homologous polypeptide and methods of making the animal.

Group VI, claims 18, 19 and 43, drawn to a transgenic animal exhibiting reduced expression of a minibrain homologous polypeptide and methods of making the animal.

Group VII, claims 20, 21 and 33, drawn to a recombinant host cell exhibiting modified expression of a minibrain homologous polypeptide and a kit.

Group VIII, claim 22, drawn to a method of identifying a polypeptide involved in the regulation of energy homeostasis or/and metabolism of triglyceride comprising binding a collection of polypeptides with a minibrain homologous protein or function fragment thereof.

Group IX, claim 23, drawn to a method of screening for an agent which modulates/effects the interaction of a minibrain homologous polypeptide with a binding target, comprising the steps of incubating a mixture comprising a minibrain homologous polypeptide or a functional fragment thereof; a binding target/agent of said polypeptide or functional fragment thereof; and a candidate agent under conditions whereby said polypeptide or functional fragment thereof specifically binds to said binding target/agent at a reference affinity.

Group X, claim 24, drawn to a method of screening for an agent which modulates/effects the interaction of a minibrain homologous polypeptide with a binding target, comprising the steps of incubating a mixture comprising a minibrain homologous polypeptide or a functional fragment thereof; a binding target/agent of said polypeptide or functional fragment thereof; and a candidate agent under conditions whereby said polypeptide or functional fragment thereof specifically binds to said binding target/agent at a reference affinity.

Group XI, claims 25 and 26, drawn to a method of producing a composition comprising mixing a polypeptide that binds to a minibrain homologous protein with a pharmaceutically acceptable carrier.

Group XII, claim 33, drawn to a kit comprising an antibody.

Group XIII, claim 33, drawn to a kit comprising an antisense oligonucleotide.

Group XIV, claim 34, drawn to a method of producing a composition comprising mixing an agent which modulates/effects the interaction of a minibrain homologous polypeptide with a binding target with a pharmaceutically acceptable carrier.

Group XV, claim 36, 39 and 41, drawn to use of for the treatment of obesity, diabetes, or/and metabolic syndrome for controlling the function of a gene or/and a gene product which is influenced or/and modified by a minibrain homologous polypeptide in a patient in need of treatment, comprising administering to the patient an effective amount of a nucleic acid molecule encoding a minibrain homologous protein or an isoform, a functional fragment or variant thereof, in particular a nucleic acid molecule as described in Table 1, particularly of a nucleic acid molecule according to claim 3 (a), .(b), or (c).

Group XVI, claim 36, drawn to use of for the treatment of obesity, diabetes, or/and metabolic syndrome for controlling the function of a gene or/and a gene product which is influenced or/and modified by a minibrain homologous polypeptide in a patient in need of treatment, comprising administering to the patient an effective amount of a modulator/effector of said nucleic acid molecule.

Group XVII, claim 36, drawn to use of for the treatment of obesity, diabetes, or/and metabolic syndrome for controlling the function of a gene or/and a gene product which is influenced or/and modified by a minibrain homologous polypeptide in a patient in need of

treatment, comprising administering to the p patient an effective amount of a modulator/effector of said polypeptide.

Group XVIII, claim 37, drawn to a method of identifying substances capable of interacting with a minibrain homologous polypeptide, particularly with a polypeptide according to claim 3, comprising using a nucleic acid molecule encoding a minibrain homologous protein or an isoform, a functional fragment or variant thereof, in particular a nucleic acid molecule as described in Table 1, particularly of a nucleic acid molecule according to claim 3 (a), (b), or (c) or/and a variant of said nucleic acid molecule.

Group IXX, claim 37, drawn to a method of identifying substances capable of interacting with a minibrain homologous polypeptide, particularly with a polypeptide according to claim 3, comprising using a polypeptide encoded thereby or/and a functional fragment or/and a variant of said polypeptide.

Group XX, Claim 37, drawn to a method of identifying substances capable of interacting with a minibrain homologous polypeptide, particularly with a polypeptide according to claim 3, comprising a modulator/effector of said nucleic acid molecule.

Group XXI, Claim 37, drawn to a method of identifying substances capable of interacting with a minibrain homologous polypeptide, particularly with a polypeptide according to claim 3, comprising a modulator/effector of said polypeptide.

Group XXII, claim 42, drawn to a method for the treatment, alleviation or/and prevention of metabolic diseases or dysfunctions, including obesity, diabetes, or/and metabolic syndrome, as well as related disorders such as eating disorder, cachexia, hypertension, coronary heart disease, hypercholesterolemia, dyslipidemia, osteoarthritis, gallstones, or liver fibrosis in a patient in need thereof, comprising administering to the patient an effective amount of a host cell as defined in claim 20.

Group XXIII, claim 44, drawn to a method for the treatment, alleviation or/and prevention of metabolic diseases or dysfunctions, including obesity, diabetes, or/and metabolic syndrome, as well as related disorders such as eating disorder, cachexia, hypertension, coronary heart disease, hypercholesterolemia, dyslipidemia, osteoarthritis, gallstones, or liver fibrosis, in a patient in need thereof, comprising administering to the patent an effective amount of an agent as identified by the method of claim 23.

The inventions listed as Groups I-XXIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Okui et al. teach a pharmaceutical composition of Dyrk1a in a 50 mM glycine Tris-HCl ph 7.4 buffer (Okui, page 166, col. 2, parag. 2).

A restriction election requirement is made for the human homologs listed in Table 1 of the specification. Each human homolog encodes a nucleic acid sequence of different nucleotide sequence that renders each member of the table patentably distinct. In such situations where patentably distinct nucleic acid or amino acid sequences are claimed or

subject matter of a claim, restriction is proper. Note this is a restriction requirement, not an election of species.

Further, should applicant elect groups XV, XVI, XVII, IXX or XX, applicant is required to elect one disease or condition.

The amendments to the claims filed October 9, 2007 have been entered. Claims 1-15, 18-26, 33, 34 and 36-44 are pending. Claims 2-10, 18-26, 33, 34 and 36-44 are withdrawn as to non-elected subject matter. Claims 1 and 11-15 are examined in this office action. Applicant elected the specific protein Dyrk1a-Isoform A.

The listing of references in the Search Report filed February 4, 2005 is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

MPEP 1893.03(g) states:

When all the requirements for a national stage application have been completed, applicant is notified (Form PCT/DO/EO/903) of the acceptance of the application under 35 U.S.C. § 371, including an itemized list of the items received. The itemized list includes an indication of whether a copy of the international search report and copies of the references cited therein are present in the national stage file. The examiner will consider the documents cited in the international search report, without any further action by applicant under 37 CFR § 1.97 and 1.98, when both the international search report and copies of the documents are indicated to be present in the national stage file. The examiner will note the consideration in the first Office action. Otherwise, applicant must follow the procedure set forth in 37 § CFR 1.97 and 1.98 in order to ensure that the examiner considers the documents cited in the international search report.

The PCT/DO/EO/903 does not indicate inclusion of reference copies. For consideration of the IDS filed February 4, 2005, applicant needs to submit copies of the references listed.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 11-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

> Definitions:
> [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf]
>
> "Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. 101. This analysis should, of course, be tempered by consideration of the context and nature of the invention. For example, if a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.

See also the MPEP § 2107 - 2107.02.

Claims 1 and 11-15 are to a pharmaceutical composition comprising a modulator or effector of a nucleic acid encoding Dyrk1a, the composition as a diagnostic composition, the composition as a therapeutic composition and the composition for the manufacture of an agent for detecting and/or verifying or for the treatment, alleviation or/and prevention of metabolic diseases or dysfunctions.

Claims 1 and 11-15 lack specific utility because at the time of filing, no diseases or conditions were known in the art to be associated with Dyrk1a. Thus, a utility for a pharmaceutical composition comprising a modulator or effector of a nucleic acid encoding Dyrk1a would not have been known in the art. Furthe r claims 1 and 11-15 lack a substantial utility because further research would be required of the skilled artisan to determine a use for a pharmaceutical composition comprising a modulator or effector of a nucleic acid encoding Dyrk1a as claimed.

At the time of filing, the art acknowledged the physiological function of Dyrk1a was unknown, although there was evidence the protein was involved in neurogenesis, and, perhaps Down's Syndrome. Human and rodent Dyrk1a genes were known to be expressed ubiquitously in adult and fetal tissues, with high expression levels in the brain and heart during development (Fotaki, page 6636, col. 2, parag. 1, lines 6-8). In Down's Syndrome patients and trisomy 21 mouse models of Down's Syndrome, overexpression of Dyrk1a is observed (Fotaki, page 6636, col. 2, lines 8-12). Further, transgenic mice overexpressing Dyrk1a exhibit a deficit in visuospatial learning and memory (Fotaki, page 6636, col. 2, parag. 1, lines 15-17). However, a role for Dyrk1a in neuronal development is suspected based on the finding that Dyrk1a overexpression enhances hippocampal cell differentiation (Fotaki, page 6637, col. 1, lines 4-10). The loss of Dyrk1a in heterozygous knockout mice suggests a role for the kinase in brain size as well as body growth and development (Fotaki, page 6646, col. 2, lines 2-6). In a pheochromocytoma cell line, Dyrk1a over expression enhances nerve growth factor-mediated differentiation of the cells by upregulating the Ras/MAP kinase signaling pathway (Kelly, page 3563, col. 1, parag. 1, lines 4-8). While these data were known at the time of filing, a physiological function for Dyrk1a, and its association with a specific disease or condition was not known at the time of filing (Ferrer, page 393, col. 1, parag. 1, lines 10-11). Thus, there was no specific utility at the time of

filing, and in order to determine such a utility, the skilled artisan would have needed to engage in additional experimentation. These two facts indicate the claimed invention lacks patentable utility as of its filing date.

The specification discloses the expression of Dyrk1a in various mouse tissues (see figures 4 (A-H). However, there is no clear association with the expression observed and a function of Dyrk1a. It is noted that alterations in expression of a particular gene do not indicate a disease or condition that can be treated, or diagnosed with a pharmaceutical composition comprising a modulator or effector of a nucleic acid encoding Dyrk1a. For the claimed invention to have a patentable use, as disclosed, in treating, preventing or diagnosing a disease or condition, a specific condition would need to be identified. All that the specification provides is that in certain mice lines, ob/ob and db/db, and wild type mice are a suggestion that Dyrk1a "plays a central role in energy homeostasis" (specification, page 50, lines 11-12). Thus, the specification provides no disclosure of a disease or condition to be treated, prevented or diagnosed. The specification provides no specific or substantial utility for the claimed invention.

As Dyrk1a has no determined function, and its relation to any disease or condition is also unknown, the artisan at the time of filing would not know how to use the claimed pharmaceutical composition comprising a modulator or effector of a nucleic acid encoding Dyrk1a in the treatment, diagnosis or prevention for any particular disease or condition. To determine a utility for the claimed invention, the skilled artisan would need to perform further research, which is prohibited under 35 U.S.C. § 101. This analysis clearly indicates the skilled artisan would not find the asserted utility of pharmaceutical composition comprising a modulator or effector of a nucleic acid encoding Dyrk1a to be specific and substantial.

Claims 1 and 11-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The first paragraph of 35 U.S.C. 112 requires that the "specification shall contain a written description of the invention." This requirement is separate and distinct from the enablement requirement. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). See also *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920-23, 69 USPQ2d 1886, 1890-93 (Fed. Cir. 2004); *In re Curtis*, 354 F.3d 1347, 1357, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004).

Claims 1 and 11-15 are to a pharmaceutical composition comprising a modulator or effector of a nucleic acid encoding Dyrk1a, the composition as a diagnostic composition, the composition as a therapeutic composition and the composition for the manufacture of an agent for detecting and/or verifying or for the treatment, alleviation or/and prevention of metabolic diseases or dysfunctions. However, the specification fails to describe by structure, chemical name or any other identifier a "modulator/effector of a nucleic acid encoding Dyrk1a." An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").Without adequate description, the skilled artisan cannot envision the structure of the compound, and, therefore, applicant has failed to convey contemplation of the claimed modifiers or effectors. The claimed invention is further troublesome with regards to written description because the modulator/effector is taught to have a use in both diagnostic and treatment methods. While the specification states the modulators/effectors of a nucleic acid encoding Dyrk1a can be antibodies, biologically active nucleic acids, such as antisense molecules, RNAi molecules or ribozymes, aptamers, peptides or low-molecular weight organic compounds (specification, page 5, lines 14-25), each of these genera of compounds have to also be diagnostic or therapeutic agents. While disclosing broad genera of compositions that may modulate a nucleic acid encoding Dyrk1a, the specification does not disclose any of these suggested modulators/effectors by a structural of physical description. Further, the written description requirement has several policy objectives. "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43

USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). "The 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005). Further, the written description requirement promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term. Without such a written description, the specification fails to convey to the skilled artisan at the time of filing possession of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

December 26, 2007